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**Section II. (Remarks)**

In response to the examiner's identification of the specification as lacking SEQ ID NOs, the specification has been amended, at pages 5-8 to insert appropriate SEQ ID NOs.

In response to the examiner's objection to claim 1 as lacking a claim number in the clean copy of the pending claims in the February 5, 2002 amendment, claim 1 has been set out with a proper claim number in the preceding section. In addition, the recital of CD30 in such claim has been corrected, consistent with the examiner's remarks.

In response to the examiner's objection to claim 11 as being an omnibus type claim, the claim has been amended to recite the antibody construct in terms consistent with claim 1.

In response to the examiner's withdrawal of claims 12-14 and 17 as being non-statutory in character, as reciting a use without setting forth affirmative process steps, claims 12-14 and 17 have been amended herein so that such claims recite appropriate method steps. On such basis, it is requested that the withdrawal of such claims be reversed.

In response to the imposition of the examiner's restriction requirement against claims 1-11, 15-16, and 18, applicants elect the Group I claims 1-6 and 15, drawn to the F<sub>v</sub> antibody construct. Such election is with traverse.

The traversal is based on the fact that claim 11 has been amended to recite the antibody construct in terms consistent with those of claim 1, as noted above. Accordingly, claim 11 is appropriately consolidated with the Group I claims.

The traversal is also asserted in respect of newly added claims 19-21, each of which requires the antibody construct of claim 1, and which therefore are also properly consolidated with the Group I claims.

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The new claims 19-21 added herein are fully consistent with, and supported by, the original disclosure of the application. For example, claim 19 is directed to the specific aspect of the invention disclosed at page 4 of the specification.

In respect of the method claims 10, 12-14, 17, 20 and 21, all of such claims relate to method of making, or method of use, of the antibody construct of the Group I claims. Accordingly, such method claims should be consolidated with the Group I claims, since the method claims, in relation to the antibody construct claims, do not meet the requirements for restriction set out in the statute, 35 USC 121, which requires that:

**"[I]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."**

The statute, regardless of any USPTO practices to the contrary, requires as a basis for legally permissible restriction that the subject matter of respective claims be both independent and distinct.

The Examiner's attention is directed in this respect to the provisions of MPEP Section 802.01 (Meaning of "Independent" and "Distinct"), which states, inter alia:

**"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect..."**

It is apparent from this provision of the MPEP that since the method claims 10, 12-14, 17, 20 and 21 require the antibody construct of the Group I claims, such method of making and method of use claims are not "independent" within the meaning of 35 USC 121, i.e., they CANNOT BE CHARACTERIZED as being "unconnected in design, operation or effect" (MPEP Section 802.01) and therefore such method claims 10, 12-14, 17, 20 and 21 are NOT properly restricted.

Further, it is pointed out that since the subject matter of the method claims 10, 12-14, 17, 20 and 21 requires the antibody construct of the Group I claims, searching of the method claims imposes

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no serious burden of searching on the Examiner, since the same antibody construct subject matter must be searched in each of the method and antibody construct claims.

According to the MPEP section 803:

**"[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP §803.**

Under the applicable criterion of this MPEP provision, the Examiner is required to submit all of the method claims 10, 12-14, 17, 20 and 21 to examination on the merits with the Group I claims.

Further, the examiner's attention is directed to the TC1600 Restriction Training Materials presented to members of TC1600 by its Restriction Team in August 2004, which is in accord with such criterion ("[T]here must be a serious burden on the examiner if restriction is required," citing MPEP §803.02, §806.04(a)- §806.04(i), §808.01(a) and §808.02).

The examiner therefore is respectfully requested to submit all of the claims 1-6, 11-15, 17 and 19-21 now pending in the application, to examination and prosecution on the merits.

In the alternative, in the event that the method claims 10, 12-14, 17, 20 and 21 are withdrawn, it is requested that same be rejoined under the provisions of MPEP 821.04 upon the finding of allowable subject matter in the Group I claims.

The special technical feature analysis of the examiner also is traversed. The novel and unobvious advance of the presently claimed invention over Hartmann is set forth at page 2, first full paragraph of the specification; Hollinger likewise is distinguishable, since Hollinger does not disclose antibodies that are specific against tumor cells, and does not show that F<sub>v</sub> constructs are capable of inducing cell lysis.

#### **Fee Payable for Added Claims 19-21**

The addition of new claims 19-21 herein increases the number of total claims beyond the number for which payment was previously made, by one. Accordingly, an added claims fee of \$25 is

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payable, and a Credit Card Authorization Form authorizing charging of the credit card specified therein in such amount, is enclosed and submitted herewith.

Authorization also is hereby given to charge the amount of any deficiency or any amount additionally payable in connection with the filing and entry of this response to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

### CONCLUSION

Based on the foregoing, the Examiner is requested to reconsider, and on reconsideration to withdraw, the restriction requirement imposed against claims 1-18 in the December 13, 2005 Office Action, and to submit all claims 1-6, 11-15, 17 and 19-21 to examination on the merits.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

Respectfully submitted,



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